

Docket No. 66766-AY-PCT-US/JE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Francis G. Fang and Shiping Xie

Serial No.: 09/903,101

Examiner: S. Wright

Filed

July 11, 2001

Group Art Unit: 1626

For

METHOD FOR PREPARING CAMPTOTHECIN DERIVATIVES

1185 Avenue of the Americas New York, New York 10036

February 25, 2002

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

RESPONSE TO SEPTEMBER 25, 2001 RESTRICTION REQUIREMENT AND PETITION FOR A FOUR-MONTH EXTENSION OF TIME

This is a Response to the Restriction Requirement issued September 25, 2001 in connection with the above-identified application. A response to the September 25, 2001 Restriction Requirement was due October 25, 2001. Applicants hereby request a four-month extension of time from October 25, 2001 to February 25, 2002. The required fee for a four-month extension of time is \$1,440.00, and a check including this amount is enclosed. Accordingly, a response to the September 25, 2001 Office Action is now due February 25, 2002 and this Response is being timely filed.

Claims 1-3 are pending in the subject application.

In the September 25, 2001 Restriction Requirement, the Examiner required restriction to one of the following allegedly distinct inventions as follows:

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I. Claims 1 and 2, compounds of formulas II and III, and Claim 3 compounds 11 H-1, 4-Dioxino[2,3-g]pyrano[3'4':6,7]indolizino[1,2-b]quinoline-12(14H)-one, 8-ethyl-2,3-dihydro-15-[(4-mehtyl-1-piperazinyl)methyl], or 11H-1,4-Dioxino[2,3-g]pyrano[3',4':6,7]indolizino[1,2-b]quinoline-12(8H, 14H)-one, 8-ethyl-2,3-dihydro-8,9-dihydorxy-15-[(4-methyl-1-piperazinyl)methyl]-(9R-cis); and

II. Claim 2, compounds of formulas IV and VI, and Claim 3 compounds 4-Ethyl-1H-pyrano[3,4-c]pyridin-8-one or 4-Ethyl-7-[7-iodo-9-[(4-methyl-piperazinyl)methyl]-2,3-dihydro-[1,4]dioxino[2,3-g]quinolin-8-ylmethyl]-1H-pyrano[3,4-c]pyridin-8-one.

The Examiner alleged that the inventions of Groups I and II are distinct, each from the other, stating that they differ in structure and/or element so as to be patentably distinct, and a prior art reference anticipating but one of the groups would not render obvious the other groups under 35 U.S.C. 103 (MPEP 806.04(f)). The Examiner stated that each group is capable of supporting its own patent, and examination of more than one of the above groups would be an undue burden as it would require additional search in both the patent and non-patent literature.

The Examiner then alleged that because these inventions are distinct on the assertion given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In response, applicants hereby elect, with traverse, Group I, claims 1, 2 and 3.

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Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. \$121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. \$803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden.

The inventions of Groups I, and II, are not independent. Under M.P.E.P. §802.01, "independent" means there is no disclosed relationship between the subjects disclosed. The inventions of Groups I, II and III are drawn to camptothecin derivatives and process for their preparation. Applicants therefore maintain that the Groups are not independent and restriction is not proper.

Furthermore, under M.P.E.P. § 803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: 1) the invention must be independent and distinct, and 2) there must be a serious burden on the Examiner if restriction is not required.

Applicant respectfully submit that there would not be a serious burden on the Examiner if restriction is not required, because a search of the prior art relevant to any of the claims of Group I would necessarily turn up the prior art relevant to the claims of Group II, and vice versa. Since there is no burden on the Examiner to examine Groups I-II together in the subject application, the Examiner must examine the entire application on the merits.

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In view of the foregoing, applicants maintains that restriction is not proper under 35 U.S.C. § 121 and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

No fee, other than the enclosed \$1,440.00 fee for a four-month extension of time, is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Assistant Commissioner for Patents, Washington, D.C., 2023).

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